

**PRE-DOSED APPLICATOR AND APPLICATOR SYSTEM INCLUDING
DISPENSING OF MULTI-PART DENTAL MATERIALS**

Field of the Invention

The present invention relates in general to the application of a material with an applicator, and particularly to the application of a chemical or medicament to a patient using a single dose pre-dosed applicator.

Background of the Invention

Many materials such as chemicals and medicaments are applied with an applicator. Typically, the material to be applied is contained in bulk form, such as a bottle or jar into which the applicator is dipped. The applicator is then moved to the area on which the material is to be applied. In many medical and dental applications, the use of such bulk containers of material is disadvantageous in that cross contamination between patients can result. Often, when more material is needed during a medical procedure, the applicator is re-dipped in the bulk container.

Many of the materials to be applied are in liquid form and may drip or spill when the applicator is dipped into a bulk container. This is messy and may even result in a hazardous condition should the materials spilled be hazardous.

Additionally, some materials may stain and be difficult to clean up.

Accordingly, there is a need for a simple, easy to use, pre-dosed single use applicator in which the material can be applied easily without the possibility of cross contamination.

Summary of the Invention

The present invention relates to an applicator pre-dosed with a material, such as a chemical or a medicament. The material is placed on an absorbent portion of the applicator and permitted to dry. The material is then in an inactive, stable state on the applicator. The material on the applicator is re-activated upon being exposed to water, saliva, liquids, or other activating materials.

In another embodiment of the invention, a package is provided containing an applicator with a stable, inactive first material thereon and a separate reservoir of an activating second material. The activating second material reacts with the stable, inactive first material to produce a reaction or beneficial result.

In another embodiment of the invention, a package is provided containing multiple applicators each with a different stable, inactive material thereon. Upon reactivating the different stable, inactive materials the materials may be

combined causing a reaction by being applied in sequence in a procedure.

Accordingly, it is an object of the present invention to provide a pre-dosed, single use applicator that is easy to use.

It is yet another object of the present invention to prevent cross contaminations between uses or patients.

It is an advantage of the present invention that the applicator or container is in a stable, inactive state on an applicator ready to be activated.

It is a feature of the present invention that material is dried on an applicator.

These and other objects, advantages, and features will become more readily apparent in view of the following detailed description.

Brief Description of the Drawings

Fig. 1 is a perspective view of an applicator having a flocked end.

Fig. 2 is a perspective view of an applicator having a foam end.

Fig. 3 is a perspective view of an applicator having an elongated flocked end.

Fig. 3A is a partial perspective view of an applicator having an elongated flocked end with a ball tip.

Fig. 4 illustrates the application of a wedge shaped flocked embodiment of the present invention.

Fig. 5 is a perspective view of an applicator having a brush end.

Fig. 6 is a perspective view illustrating a package containing a first inactive material on an applicator and a separate second activating material.

Fig. 7 is a cross section illustrating a capsule having a first inactive material on an applicator and a separate reservoir of an activating second material.

Fig. 8 is a cross section of another embodiment of a capsule of the present invention having a foam applicator end.

Fig. 9 is a cross section of another embodiment of a capsule of the present invention having a brush applicator end.

Fig. 10 schematically illustrates another embodiment of the present invention utilizing an applicator tip and a syringe.

Fig. 10A schematically illustrates another embodiment of the present invention utilizing an applicator tip and a syringe.

Figs 11A-D schematically illustrates the preparation of an embodiment of the present invention.

Fig. 12 is a block diagram illustrating the method steps of the present invention.

Figs. 13 and 14 schematically illustrate the preparation of another embodiment of the present invention.

Fig. 15 illustrates another embodiment of the present invention having a multi-chamber package.

Fig. 16 illustrates reactivating a multi-component embodiment of the present invention.

Fig. 17 illustrates application of a multi-component embodiment of the present invention.

Detailed Description of the Preferred Embodiments

Fig. 1 illustrates a pre-dosed applicator 10 having a handle 12 and a hinge or neck 14. Adjacent hinge or neck 14 is a tapered end 16 terminating in a flocked applicator end 18. The flocked applicator end 18 contains a multitude or plurality of flocks, hairs, or small bristles adhered to the tapered end 16. The tapered end 16 may have a ball at the end. The flocked applicator end 18 is pre-dosed with a material by dipping or otherwise coating the flock 18 with a liquid material and permitting the liquid to dry to an inactive state. After drying, the material is rendered stable and inactive, ready to be re-activated. The inactive material may

be re-activated with a second activating material or upon exposure to a solvent or moisture at the site to be applied.

For example, in dentistry, an indicating liquid is often used to detect caries or decay in teeth. The indicating liquid is a dye which, when placed onto tooth decay and rinsed off, will stain any areas that are diseased or decayed. The dye is often messy and can permanently stain many unintended surfaces. The indicating material may be dried onto the flock 18. The indicating material is then re-activated by exposure to water or saliva, or other solvent. Any material that may be dried and re-activated may be used on the pre-dosed applicator.

Fig. 2 illustrates another embodiment of the present invention using a foam applicator end. The pre-dosed foam applicator 110 has a handle 112 and a hinge or neck 114. Adjacent the hinge or neck 114 is a tapered end 116. Attached to the tapered end 116 is a foam applicator 118. The hinge 114 permits the tapered end 116 to be bent or angled relative to the axis of the handle 112. This helps in the positioning of the foam applicator end 118. The foam applicator end 118, as in the embodiment illustrated in Fig. 1, is pre-dosed with a material that is dried and capable of being re-activated. The foam applicator end 118 may also be made of other absorbent materials such as cotton, fabric, or any other

equivalent absorbent material capable of holding a liquid material that is dried and re-activated.

Fig. 3 is another embodiment of the present invention that may be utilized as a dental wedge, toothpick, or gum or gingival stimulator. The pre-dosed wedge applicator 210 comprises a handle 212 with a hinge or neck 214. Adjacent the hinge or neck 214 is a tapered end 216. A flock 218 is adhered to a substantial portion of the tapered end 216. The longitudinal extent of the flocked wedge portion 218 is at least the width of a tooth or approximately 0.25 to 2.00 centimeters.

The flocked wedge portion 218 may be pre-dosed with an astringent or hemostatic agent. The astringent or hemostatic agent, after drying, becomes stable and inactive. The flocked portion 218 may also be pre-dosed with an abrasive, such as zirconium silicate. In this embodiment the applicator 210 may be used as a substitute for dental floss to clean between the teeth. The flocked wedge portion 218 may also be impregnated with an abrasive material.

The flocked portion 218 may also be pre-dosed with an antiseptic, antibiotic, or analgesic material. Of course, the flocked portion 218 may be any absorbent substance capable of absorbing or holding the dry material to be later re-activated. For example, the absorbent substance may be flock,

cotton, foam, bristles, or any other substantially equivalent absorbent substance.

Fig. 3A illustrates another embodiment of the present invention having a ball end. The pre-dosed applicator 210A comprises a handle 212A with a hinge or neck 214A. Adjacent the hinge or neck 214A is a tapered end 216A. The tapered end in this embodiment is rounded or an elongated cone. A flock 218A is adhered to a substantial portion of the tapered end 216A. The longitudinal extent of the flocked wedge portion 218A is at least the width of a tooth, or approximately between one and two centimeters. A ball 219 is placed on the end of the tapered end 216A. The ball 219 prevents injury to the gingival or gums. The flocked wedge may also be used as a tooth cleaner, toothpick or gingival stimulator. When used as a toothpick or gingival stimulator, the wedge shaped applicator may be pre-dosed with flavors, disinfectants, antiseptics, antibiotics, analgesics, or other similar equivalent materials. When used as a toothpick or gingival stimulator the flocked wedge portion or tapered end 216A is used to clean between the teeth without any pre-dosed material. The flock 218A preferably extends from the distal end at ball 219 to the neck 214A. The neck 214A facilitates bending the tapered end 216A.

Fig. 4 illustrates the application of another embodiment of a wedge applicator in use. The wedge applicator

210' comprises a flocked wedge portion 218' placed on a wedge shaped portion 216'. A handle 220 may be used to facilitate insertion and removal of the wedge applicator 210'. The wedge applicator 210' is placed between the teeth 24 and 26.

Gingiva, tissue, or gum 22 is adjacent the base of the teeth 24 and 26.

A pre-dosed wedge is beneficial in many dental procedures. Wedges are typically used in dentistry. Wedges are used in class two cavity preparation restorations. In a class two cavity, adjacent sides of the back or posterior teeth are involved. Upon the removal of decay, it is necessary to use a matrix band to contain the stored material. The matrix band is a band of metal surrounding the tooth. A wedge is used to hold the matrix band against the bottom of the cavity preparation. This prevents excess filling material from being forced behind the prepared cavity. Improperly positioned matrix bands can result in a restoration that is susceptible to periodontal infections or other problems. It is often advantageous to keep the preparation dry during placement of the restorative material. A flocked wedge pre-dosed with an astringent or hemostatic agent, when in position, is reactivated and aids in keeping the gum lines clear and the prepared cavity preparation dry. The natural absorbency of the flocked material will aid in keeping the preparation dry. Additionally, the flocked wedge or tapered end may be used

without any pre-dosed material or astringent or hemostatic agent.

Fig. 5 illustrates another embodiment of a pre-dosed brush applicator 310. This embodiment comprises a handle 312, a hinge or a crimp 314 placed adjacent an end portion having a brush 318 formed therein. The brush 318 may be pre-dosed with an inactive stable material. The material may then be re-activated for use or to apply the re-activated material.

Fig. 6 illustrates another embodiment of the present invention illustrating a package having an inactive first material and an activating second material. A pre-dosed applicator 10 having a handle 12 is placed within a tray 28. The tray 28 has an applicator well 32 and a material well 36 formed therein. The tray 28 may be made of a suitable plastic material. The applicator 10 is held within the applicator well 32 of tray 28 and has an applicator end 18 that is pre-dosed with a first inactive stable material. The applicator end 18 may be a brush as illustrated, or a flock, sponge, or other equivalent material. The activating material well 30 contains an activating second material 36. A cover 34 may be used to seal the top surface of tray 28 protecting the pre-dosed applicator 10 and the second activating material 36.

In use, the pre-dosed applicator 10, which is pre-dosed with an inactive stable material on the applicator end 18, is removed from the tray 28 and dipped into the activating second

material 36. The activating second material 36 works in cooperation with the first initially inactive stable material on the applicator end 18 of the pre-dosed applicator 10 so as to when activated and combined result in forming an activated material with the desired properties. The activating second material 36 may be a solvent such as alcohol, acetone or any another chemical agent that has a reaction with the first initially stable inactive material on the applicator end 118 of the pre-dosed applicator 10. Accordingly, many two-part component materials may be conveniently packaged and used in a single dose applicator.

Figs. 7-9 are cross-sections of capsule embodiments of the present invention. Fig. 7 is a cross section of a capsule embodiment of the present invention. Capsule 38 comprises a body 40 having a discharge end 42. Placed in the discharge end 42 is a cannula 44. Cannula 44 is preferably made of a malleable metal. A flocked applicator end 46 is placed on the distal end of the cannula 44. The flocked applicator end 46 is pre-dosed with a first stable inactive material. A second activating material 48 is placed within the body 40 of capsule 38. A piston 50 seals the rearward open end of the body 40. A flange 52 is placed adjacent the open end of body 40 so as to attach to a dispenser, not illustrated. In this embodiment, upon advancing piston 50, the second activating material 48 is dispensed through cannula 44 and through the flocked

applicator end 46, combining with the inactive stable material on the flocked applicator end 46. Accordingly, two component or two-part materials may be dispensed easily without any pre-mixing.

Fig. 8 is a cross section of another embodiment of a capsule 138. Capsule 138 has a body 140 with a discharge end 142. Placed within discharge end 142 is a cannula 144. Attached to cannula 144 is a foam applicator 146. The open end of the body 140 is sealed with a piston 150. Adjacent the open end of body 140 is a flange 152. A second activating material 148 is placed within the body 140. The co-action of the first material contained within the foam applicator end 146 and the second material 148 contained within the body 140 results in the two material being combined and activated, having a desired therapeutic effect.

Fig. 9 is yet another embodiment of a capsule of the present invention. Capsule 238 comprises a body 240 having a discharge end 242 with a cannula 244 placed therein. Within cannula 244 are bristles 246 forming a bristle brush. The open end of the body 240 is sealed with a piston 250. The bristles 246 are pre-dosed with a stable inactive first material. The body 240 contains a second stable inactive material 248. Upon advancing the piston 250 towards the discharge end 242, the second material 248 is forced through cannula 244 and through bristles 246. The combining of the first and second materials

results in activation of the materials to obtain a desired action.

There are many well-known two-part materials that when combined or mixed form a desired reaction. Such materials may be sealants, adhesives, hemostatic agents, whitening agents, and numerous other equivalent two-part materials that when combined form a material having desired properties.

Fig. 10 illustrates another embodiment of the present invention. In this embodiment, an empty tip 338 may be attached to a syringe 354 by an attachment means 353. The mating or attachment means 353 of the empty tip 338 and the syringe 354 may be accomplished by any equivalent known attachment structure, such as a Luhr lock conventionally used on syringes. The tip 338 may also simply be press-fit onto the discharge end 352 of the syringe 354. Threads or a bayonet type structure may also be used as means for attaching the tip 338 to the syringe 354. Other equivalent attachment means may be used to hold the tip 338 onto the syringe 354.

The tip 338 comprises a discharge end or nozzle 344 having a flocked applicator end 346. The flocked applicator end 346 contains a first stable inactive material. A bore 360 placed within the tip 338 communicates to the open discharge end of the syringe 354. The syringe 354 has a syringe body 356 and a syringe plunger 358. Contained within the syringe 354 is a second material 348.

In use, the second material 348 may be contained in bulk in the syringe 354. The empty tip 338 may then be placed or attached onto the syringe 354 with the second material 348 being dispensed through the bore 360 within the tip 338. The second material contacts the pre-dosed flocked applicator end 346 containing a first material. This results in a co-action of the two materials to activate the materials producing a desired result or reaction. In this embodiment, multiple empty tips 338 may be combined with use of a single bulk syringe 354. Therefore, the single bulk syringe 354 may contain a number of doses to be dispensed with a plurality of empty tips 338 having a pre-dosed flocked applicator end 346.

Fig. 10A illustrates another embodiment of the present invention. In this embodiment, an empty tip 338' may be attached to a syringe 354' by an attachment means 353'. In this embodiment the attachment means 353' is a press-fit. Other equivalent attachment means may be used to hold the tip 338' onto the syringe 354'.

The tip 338' comprises a cannula discharge end 344' having a flocked applicator end 346'. The cannula discharge end 344' may be made of a soft ductile metal that may be easily bent into a position. The flocked applicator end 346' contains a first stable inactive material therein. A bore 360' placed within the tip 338' communicates to the open discharge end of the syringe 354'. The syringe 354' has a syringe body

356' and a syringe plunger 358'. Contained within the syringe 354' is a second material 348'.

Figs. 11A-D schematically illustrate the manufacturing process for making an embodiment of the present invention. Fig. 11A illustrates dipping an applicator 10' into a container 60 holding a solution or suspension 62 containing a material intended to be applied with the applicator 10'. The flocked end 18' of the applicator 10' absorbs a portion of the solution or suspension containing the material. Fig. 11B illustrates drying the dipped flocked end 18'. A fan 64 may be used to dry the flocked end 18' of applicator 10'. Fig. 11C illustrates the flocked end 18' of the applicator 10' having dried material 62' from the solution or suspension contained within the flocked end 18'. When desired the material 62' in the flocked end 18' may be reactivated and applied. The material 62' may be reactivated by dipping the flocked end 18' into a solvent for the material 62' or may be reactivated in the environment in which the applicator 10' is used. For example, saliva in a patient's mouth may activate the material 62' to be applied to a tooth. Fig. 11D illustrates applying the material on the flocked end 18' of the dosed applicator 10' to a tooth 26'. While Figs. 11A-D illustrate the use of an applicator 10' having a flocked end 18', any equivalent type of applicator may be used. For example, a brush, sponge, or cotton swab type applicator may be used.

Fig. 12 illustrates the method steps in an embodiment of the present invention. Box 410 represents the step of applying a first material to an applicator. Box 412 represents the method step of drying the material on the applicator. Box 414 represents the method step of activating the dried material. Box 416 represents the step of applying the activated material.

Another embodiment of the present invention is illustrated in Figs. 13-17. In this embodiment, multi-part materials requiring sequential application may be easily applied. Any number of multi-parts of a material may be used that react when combined. For example, one, two, three or more parts may be combined. As an example, this embodiment is particularly well suited for applying a two-part dental desensitizer. In the two-part dental desensitizer procedure a first component is applied to a tooth surface and subsequently a second component is applied to a tooth surface, the two components are combined reacting with the tooth providing an effective desensitizer. Such a two-part or two step dental desensitizer for treating tooth hypersensitivity is disclosed in United States Patent 5,874,066 entitled "Method and Kit for Treating Tooth Hypersensitivity" issuing to Hack et al on February 23, 1999, which is herein incorporated by reference.

Fig. 13 illustrates a first container 560A and a second container 560B. The first container 560A contains a first solution or suspension 562A. The second container 560B contains a second solution or suspension 562B. A first applicator 510A having an applicator end 518A is dipped into the first solution or suspension 562A. The applicator end portion 518A may be made of any absorbent material such as a brush, flock, sponge, or fiber. A second applicator 510B having an applicator end 518B is dipped into the second solution or suspension 562B. The applicator end 518B may be made of any absorbent material similar to that of the first applicator end portion 518A. The applicator end portions 518A and 518B are thoroughly soaked within their respective solutions or suspensions 562A and 562B.

Fig. 14 illustrates the first and second applicators 510A and 510B with their associated applicator ends 518A and 518B being dried with a fan 564. The applicator end portions 518A and 518B may be dried by any means such as by being air dried, freeze dried, or dried with elevated temperature or heat. The active material in the first and second solution or suspensions 562A and 562B after drying remain in a solid or crystalline form on the first and second applicator ends 518A and 518B. The applicators, being pre-dosed with a dried material, can easily be packaged, preventing the possibility of any leakage of liquid, as well as providing a longer shelf

life because the dried chemical materials are inactive or dormant.

Fig. 15 illustrates a multi-chambered package 528. The multi-chamber package may be made of any convenient material such as paper, foil, plastic, or any other suitable material for containing the materials intended to be held therein. The multi-chamber package 528 comprises a first chamber 530A and a second chamber 530B formed from two sheets of material that are sealed along the perimeter with a divider seal 532. The divider seal 532 separates the two chambers 530A and 530B. A portion of the multi-chambered package 528 may be readily separable or opened so as to provide access to the initially sealed first and second chambers 530A and 530B. Flaps 534 and 535 may be separated to gain access to each of the first and second chambers 530A and 530B of the multi-chambered package 528. The applicator 510A may be initially sealed within the first chamber 530A and the second applicator 510B may be initially sealed within the second chamber 530B.

The multi-chambered package 528 may be made relatively inexpensively, relative to other packaging required to hold liquids. Accordingly, multi-chambered package 528 does not necessarily require the strength and integrity of sealing, as would be required for a package containing a liquid material.

The applicator end portions 518A and 518B of the respective applicators 510A and 510B contain a dried or

dehydrated first and second material respectively. The applicators 510A and 510B are initially sealed within the multi-chambered package 528 by closing over flaps 534 and 535. Prior to use and reactivation of the dried first and second material on the first and second applicator end portions 518A and 518B, the multi-chambered package 528 is opened by separating the flaps 534 and 535. The applicators 510A and 510B can then be removed.

Fig. 16 illustrates reactivating or re-hydrating the dried material on the applicator end portion 518A and 518B. A container 560 contains a liquid 562. The liquid 562 may be any solvent, which will reactivate the dried material on the applicator end portion 518B. For example, the liquid 562 may be warm water. The use of warm water is advantageous because it will result in less thermal shock to tissues and be more comfortable for a patient. Additionally, the warm water or other solvent assists in the reconstitution or reactivation of the dried material. Just prior to use, the applicator end portion 518B is dipped into the liquid 562, activating or re-hydrating the first component of the multi-part or component material for application.

Fig. 17 illustrates the application of the multi-part components in a dental procedure, such as in the treatment of hypersensitivity of teeth. After being activated or hydrated, the first component material on the applicator end portion

518A is applied to the teeth 524 and 526 near where the teeth 524 and 526 meet the gingival or gum 522. The material may also be used in other portions of the teeth 524 and 526. After application of the first component part, a second component part is applied with applicator 510B. The applicator end portion 518B contains a reactivated or re-hydrated second component part, which is supplied in the same vicinity as the first component part of material so as to react therewith. As a result, multiple different parts of a material may be easily applied in a multi-component material in a dental procedure to provide effective treatment.

While any multi-component material may be used with the present invention, this embodiment of the present invention is particularly applicable to multi-part dental desensitizers that, when the two parts are combined, form crystals that are effective in the treatment of dental hypersensitivity. This embodiment of the present invention solves the problem of packaging a unit or single dose of material used in a dental or medical procedure. It is often difficult to securely contain and easily dispense small quantities of liquid material as is required in unit or single dose quantities of material. Additionally, small quantities of liquid material may deteriorate and become ineffective over a relatively short period of time. This greatly reduces the shelf life of liquid materials contained in small quantities.

Accordingly, although the preferred embodiments have been illustrated and described, it will be obvious to those skilled in the art that various modifications may be made without departing from the spirit and scope of this invention.